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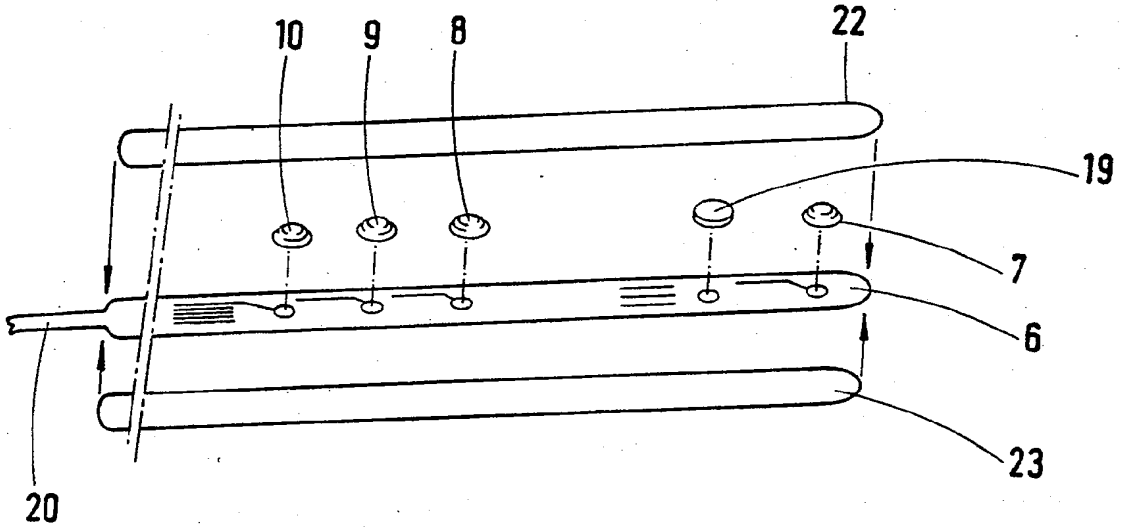
(54) Title: INTRAUTERINE PROBE



(57) Abstract

An intrauterine probe for monitoring fetal heart rate (FHR) during labour comprises an elongate, flexible strip-like base member (6) formed from electrically insulating material and having at least two, longitudinally spaced electrodes (7, 8, 9, 10) located in one face thereof, each electrode protruding sufficiently from the face of the base member so that it can be pressed into direct contact with fetal skin and having a portion of insulating material (4) between the electrodes whose profile is such that in use, a thin electrolyte film of amniotic fluid having a high impedance is formed between the electrodes.

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INTRAUTERINE PROBE

This invention relates to an intrauterine probe which is suitable for use in monitoring conditions during labour, i.e. the condition of the fetus and also the condition of the mother.

The desirability of monitoring fetal heart rate (FHR) and intrauterine pressure (IUP) during a difficult labour is well known. In practice, IUP has been measured using a pressure catheter, and a separate device has been used to monitor FHR. Generally, FHR has been monitored by recording the voltage between two electrodes of which one is in the form of a body clip and the other (the "indifferent" or "reference" electrode) is spaced a short distance from the clip in contact with surrounding tissue (usually maternal).

The clip is attached to that part of the fetus which is presented for delivery. Normally, therefore, it is a scalp clip. A clip is necessarily invasive to the fetus, and is a disincentive to routine monitoring during labour. It is desirable clinically to carry out fetal monitoring routinely but this is unlikely to be achieved unless the procedure can be made more acceptable to women.

It would also be desirable to devise a system which would enable FHR and other factors to be monitored without the need to make separate trans-vaginal insertions.

According to the present invention there is provided an intrauterine probe for monitoring fetal heart rate (FHR) during labour which comprises an elongate, flexible

flattened body member formed from electrically insulating material and having at least one electrode located in one face thereof, each electrode being located close to the face of the body member so that it can be pressed into close proximity with fetal skin and having a portion of insulating material surrounding the electrode whose profile is such that in use, a thin electrolyte film of amniotic fluid having a high impedance is formed between the electrode and the fetal skin.

Preferably, there are at least two electrodes and the geometry of the portion of insulating material between the electrodes is such that, in use, a thin electrolyte film of amniotic fluid is trapped between the fetal skin and the area of probe between the electrodes.

We have found that consistent and reliable signal detection can be achieved using the probe according to the invention, which is at least comparable with that from a conventional fetal scalp clip electrode.

According to a further aspect, the invention provides a method of monitoring FHR during labour which comprises introducing into the cervix a probe comprising an elongate, flexible, flattened body member formed from electrically insulating material and having at least one electrode located in one face thereof so that it can be pressed into close proximity with the fetal skin and analysing the signal output from the electrode and a reference electrode by discriminating the fetal heart rate from the maternal heart rate on the basis of difference in ECG signal 'R' wave width

or frequency.

Improved signal detection is achieved by maximising the impedance between the 'active' electrode and the 'reference' electrode. Wide spacing of the reference and active electrodes along the length of the probe contributes to this end. However, the most effective measure to maximise impedance is to design the profile of the face of the probe so as to achieve a thin 'electrolyte' film of amniotic fluid between the electrodes, while ensuring that the electrodes are in fetal skin contact. If the probe profile which surrounds the electrodes has a generally flat top or slightly rounded shape (when seen in cross-section), a thin film thickness of the order of 0.5 mm or less may be achieved. Preferably, the upper surface of the electrode lies substantially in the same plane as the surface of the probe body. However, in a slightly less preferred embodiment the top surface of the electrode is located just beneath the plane of the probe surface.

From the standpoints of (FHR) measurements and utero-cervical anatomy, the probe should satisfy certain criteria. The body of the probe is formed from an electrically non-conductive and non-toxic flexible material. It should be stiff/resilient enough to enable it to be inserted, by pushing from the proximal end through the cervix and around the fetal head. However, it should not be springy but sufficiently flexible and floppy so that it will lie along the surface of the fetus when inserted into the uterus.

The probe is generally flat in cross-section with

rounded edges and with the electrodes located in the surface of one face. The flat sides enable the easy positioning of the electrodes, while fulfilling the requirement of surrounding the electrodes with insulating material. The shape also confers probe flexibility along the surface lying against the fetus, while providing sufficient transverse rigidity to allow the clinician to have control over the direction of insertion.

Details of construction and operation of intrauterine probes in accordance with the invention will be apparent from the following description and accompanying drawings in which:-

Figure 1 is a perspective view of an embodiment of a probe in accordance with the invention,

Figure 2 is a cross-sectional view through an electrode of the probe of Figure 1,

Figure 2A is a cross-sectional view through the probe between electrodes,

Figure 3 is a schematic section of a uterus showing the probe in use,

Figure 4 is a diagrammatic exploded view illustrating one method of manufacturing the probe,

Figure 5 is an exploded view of a pressure sensor on an enlarged scale,

Figure 6 is a schematic representation of the connection of the electrodes to a signal processor,

Figure 7 is a typical trace showing the fetal and maternal heart beats.

Referring to the drawings and in particular Figures 1 2 & 2A, the probe comprises an elongate body 1 about 40 to 50 cms in total length. As best seen in Figures 2 & 2A, the probe has a flattened configuration with rounded edges 2, 3 and generally flat upper and lower faces 4,5. Typically, the probe is about 1 cm wide and about 3 mm thick. A flexible printed circuit board 6 carries spaced electrodes e.g. of stainless steel 7, 8, 9 & 10 each having a domed head 11 and is encapsulated in a flexible plastics potting compound, such as a 2-part polyurethane composition. The dimensions and inherent flexibility of the plastics material are such that the probe takes up the position shown in Figure 3 when inserted in the uterus. The particular potting composition employed was a 2-part polyurethane composition obtainable from Emerson & Cumming Ltd. 866 Uxbridge Road, Hayes, Middlesex, under the trade name CPC 19 flexible polyurethane potting compound. Probes having a stiffness (Young's Modulus) in the range of 1 to 10 meganewtons per square metre are suitable.

As shown in Figure 2, the domed head 11 of the electrode 8 is effectively shrouded by rounded portions 12 & 13 of the insulating material of the body. The surface of the domed portion 11 lies substantially in the same plane as the flat face 5 of the body. In use, this ensures that amniotic fluid is squeezed out to form a thin electrolyte film between the electrode 8 and the reference electrode when the probe is suitably located in relation to the uterine or cervical walls.

As can be seen from Figure 1, the electrodes are spaced so that the distal electrode 7 is spaced from the other electrodes 8, 9 & 10. As a consequence, the distance between electrode 7 and its nearest electrode 8 is greater than the inter-electrode spacing in the group of electrodes 8, 9 & 10. Because of its greater spacing the electrode 7 is generally used as the reference electrode. However, as will be described below, the signals detected by any pair of electrodes may be used for measuring the FHR. The spacing between electrode 7 and electrode 8 may typically be 8 to 12 cms, while the inter-electrode spacing in the group of electrodes 8, 9 & 10 may be, for example, 3 to 6 cms. As the birth progresses, the signals detected by each electrode may vary in strength and the signals may be processed by selecting, at any one time, the outputs from the pair of electrodes which give the best signal.

In contrast with the experience of scalp-clip monitors, the quality of the signals obtained from the probes of the invention often improve as the birth progesses. This is believed to be because the probe is pressed more firmly against the baby's back as the fetal head passes into the birth canal.

Referring again to Figure 2, the portion of insulating material surrounding the electrodes may be formed from a unicellular or closed cell foam. These portions 15 & 16 are shown in cross hatching in Figures 2 & 2A. This may enable the probe to be pressed less tightly against the fetal skin while still minimising the effective

'electrolyte' film thickness.

Manufacture of the probe is illustrated in Figure 4. The electrodes 7, 8, 9 & 10 and also a pressure transducer 19 are attached to a printed circuit board 6. Board 6 includes conductor strips linking the electrodes to a multifilament cable 20 which is connected to a processor (see Figure 6). Conveniently, the processor may include a digital display unit but may incorporate an oscilloscope and a chart recorder (not shown). Circuit board 6 and attached electrodes are encapsulated in a potting compound to form a shaped probe body having the configuration shown in Figures 1, 2 & 2A by moulding between upper and lower moulds 22 & 23. A foaming agent may be introduced into the potting composition, or into a portion which will form the parts 16 & 17 of the probe body (see Figure 2).

The minimum number of electrodes in the group 8, 9 & 10 is one but the more electrodes are present, the better the chance of maintaining good signal quality during birth. Generally 2 to 4 electrodes in the group are usually satisfactory. The group of electrodes are preferably spaced over a distance sufficient to encompass the fetal head and neck, e.g. at least about 5 cms, typically 5 to 15 cms. Interelectrode spacing is generally less than the distance between the electrode nearest the tip, i.e. electrode 8, and the distal electrode 7. This distance is commonly about 15 to 20 cms, e.g. about 18 cms. At present, the preferred configuration is a distal electrode 7 and three equally-spaced additional electrodes 8, 9 & 10.

The interelectrode spacing being about 5 cms and the spacing from the distal electrode 18 cms.

In use, therefore, one at least of the group of electrodes 8, 9 & 10 is to a large extent redundant. At least one of the electrodes in the group will be useful, depending to some extent on the length of the fetus, and fetal movement after insertion. Sometimes two of the electrodes in the group will be utilised.

A probe of the invention can be used from the time at which the cervix is dilated to, say, 1 cm. The probe is inserted around the head or neck of the fetus and towards its lower trunk, and the flattened shape ensures that one face is stably oriented in contact with at least the head of the fetus. The intention is that the probe should be inserted to the extent that the distal electrode is on or adjacent to the lower trunk of the fetus, while one at least of the group of electrodes is in good contact with the head or neck of the fetus (see Figure 3). At a later stage of labour to that shown in Figure 3, the fetus' head and neck will be pressed against the electrodes 8, 9 & 10.

A probe of the invention in its preferred form includes a pressure sensor specifically to measure Intrauterine amniotic fluid Pressure (IUP). The location of this sensor is such that the point at which IUP is measured is both reasonably well known and unlikely to be influenced by unknown causes. By contrast with a pressure catheter, a pressure transducer and other sensors operating as miniature load cells (force sensors) for use in the invention can be

constructed very cheaply.

Preferably the IUP sensor 19 is located at or close to the distal end of the probe. Its internal construction is shown in Figure 5 and comprises a base carrier 30 which may be manufactured in metal (e.g. stainless steel), but is preferably moulded from plastics material (e.g. ABS plastic) and supporting a cantilever strain gauge (sensor) 31. The output from the strain sensor is connected to the printed circuit board 6. Overlying the base carrier is an assembly 33 comprising an annular thin film membrane 34 which supports a rigid plastics disc 35. The pressure sensor is completed by a sealing ring 36, which may be moulded in a rigid plastic e.g. ABS, or in a soft rubber-like material, over the base carrier and may include a grid structure to protect the membrane. In use, variations of IUP will cause the disc 35 to move inwardly and outwardly, thus applying more or less force to the strain gauge 31 via a contact button 37.

A probe of the invention provides a single device for the measurement of those criteria which are presently considered to be important for the good health of the mother and her baby. The probe can also be used, without changing its essential function, to measure further or different parameters; for example, there may be a temperature sensor which could be used to detect maternal hyperthermia or temperature variation during contraction, and/or an optical sensor which could be used to detect, say, meconium and/or fetal blood oxygen levels when used as a

trans-cutaneous oximeter.

For use, a probe of the invention is in connection with a processor and display means. An arrangement for processing and displaying the output from the probe is shown in Figure 6. Typical traces produced by a chart recorder connected to a probe in accordance with the invention are shown in Figure 7. The output from the electrode pairs is a mixture of maternal and fetal heart rates and background 'noise' deriving from other muscular activity. The specific processing to distinguish the maternal and fetal ECG complexes takes advantage of the differing morphologies of each. Results with the invention have demonstrated that the relative amplitudes of the fetal and maternal complexes during a given labour are unpredictable but the measured width of the fetal complex is consistently less than that of the maternal complex during the same labour. Hence, either frequency domain pattern recognition of the spectral components (amplitude and/or phase) after Fourier transformation of each complex, or temporal/spatial pattern recognition in real time and/or by retrospective analysis can be applied. Although the fetal heart rate signal cannot always be recognised uniquely by the measured width of its 'R' component, a combination of R wave width recognition in conjunction with comparison with a stored pattern can be used to separate unambiguously the fetal and maternal heart rates from each other and from background noise. In this way, those signals recorded by the electrodes processed in order to provide separate displays of FHR and MHR, together

with the data obtained from the IUP sensor and other sensors at least. The display is visual, e.g. on a screen, but for the purposes of record a chart recorder will be used (no other display may be necessary). Alternatively, the processed fetal heart signal and IUP can be made compatible with current commercial fetal monitors from which the FHR and IUP can be presented in the normal way.

Figure 6 shows an arrangement in accordance with the invention for processing and displaying the signals detected by the probe.

Signals from the electrodes are fed to a multi-channel ECG amplifier and the amplifier output connected to the processing equipment via a patient isolation link such as a fibre optic cable. The transmitted signals are re-amplified and then passed to a signal selector which monitors the signals and selects the best signals from any pair of electrodes. The selected signal is passed via a data store to a band width filter and a low pass filter (to establish the isoelectric line for the wave form). A feed-back to the signal selector is provided via a signal quality monitor to enable the signal selector to select signals on the basis of quality of fetal heart signal content as well as signal strength. After processing by an ECG pattern recognition unit, the signals are separated by an ECG R wave width discriminator into the fetal and maternal signals and the outputs displayed on rate meter display units, such as digital display units.

CLAIMS

1. An intrauterine probe for monitoring fetal heart rate (FHR) during labour which comprises an elongate flexible, generally floppy flattened body member formed from electrically insulating material and having at least two, longitudinally spaced electrodes located in one face thereof, each electrode being located in the face of the body member so that it can be pressed into close proximity with fetal skin and having a portion of insulating material between the electrodes whose profile is such that in use, a thin electrolyte film of amniotic fluid having a high impedance is present between the electrodes.

2. A probe according to claim 1 in which each electrode is located in a cavity in the base member and is shrouded by portions of insulating material which are shaped to force out amniotic fluid from the region surrounding the electrode.

3. A probe according to claim 2 in which the portions of insulating material surrounding the electrodes are formed from a resilient foam material having non-communicating cells.

4. A probe according to claim 2 or claim 3 in which the portions of insulating material bounding the electrodes have a rounded upper surface in cross-section.

5. A probe according to any one of the preceding claims having a distal electrode and two or more additional electrodes located in a group, the spacing between the distal electrode and the proximal additional electrode

being greater than the spacing between additional electrodes in the group.

6. A probe according to claim 5 which also includes a pressure transducer located in the region of the distal electrode.

7. A probe according to any one of the preceding claims in connection with a processor which is adapted to distinguish between signals representing FHR and maternal heart rate.

8. A method of monitoring FHR during labour which comprises introducing into the cervix a probe comprising an elongate, flexible, flattened body member formed from electrically insulating material and having at least one electrode located in one face thereof so that it can be pressed into close proximity with the fetal skin and analysing the signal output from the electrode and a reference electrode by discriminating the fetal heart rate from the maternal heart rate on the basis of difference in R wave signal width or frequency.

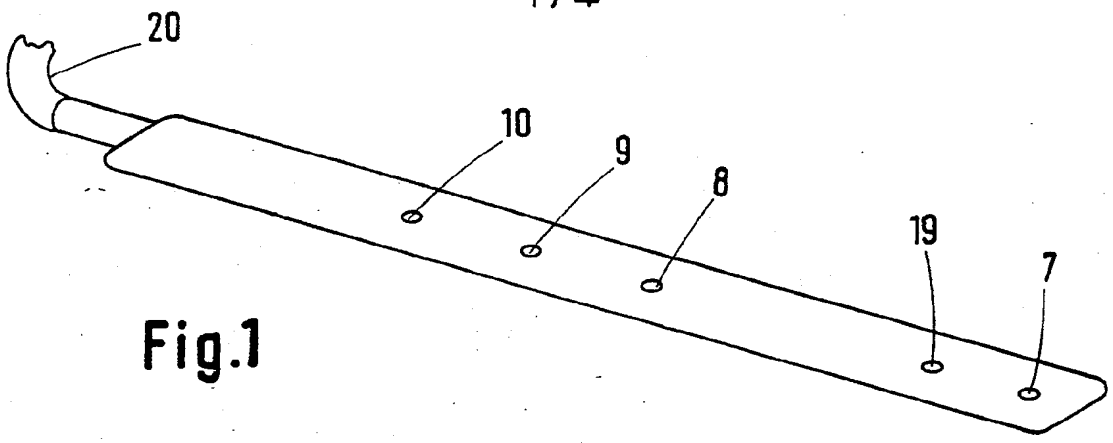


Fig.1

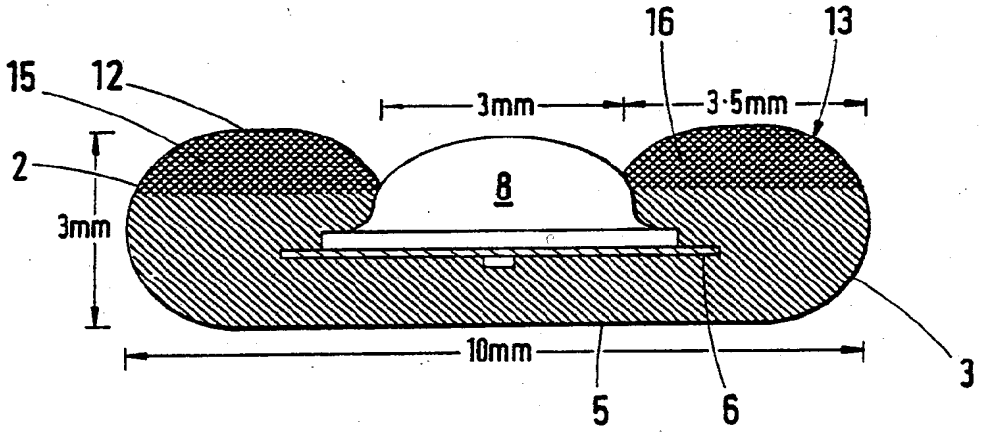


Fig.2

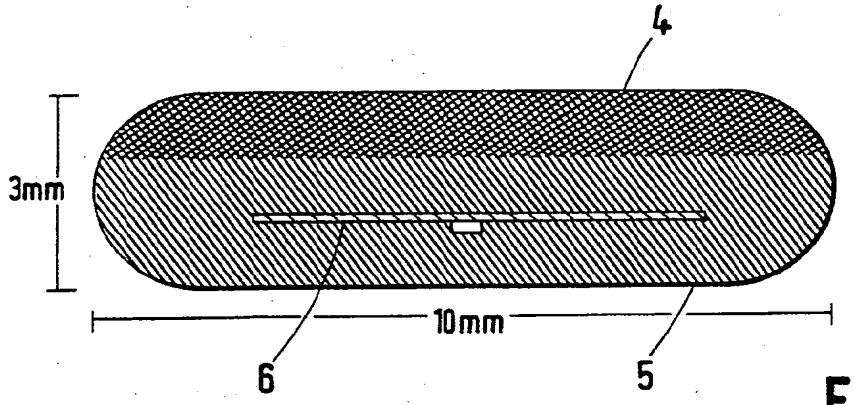
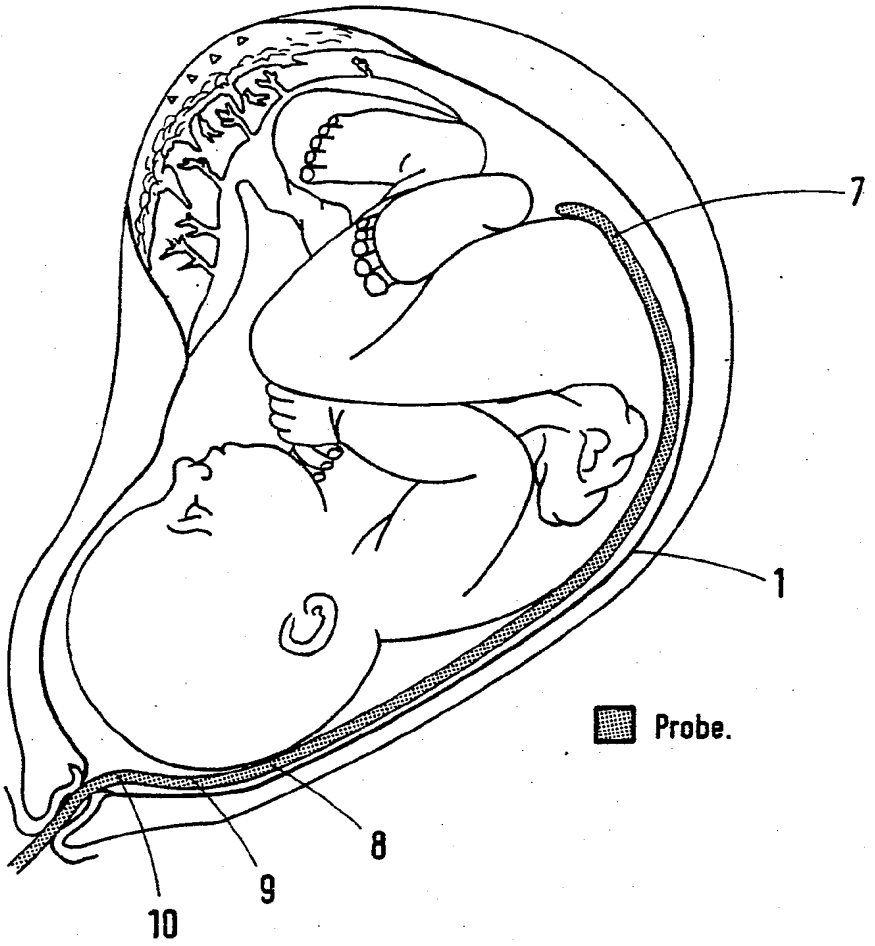


Fig.2a

Fig.3



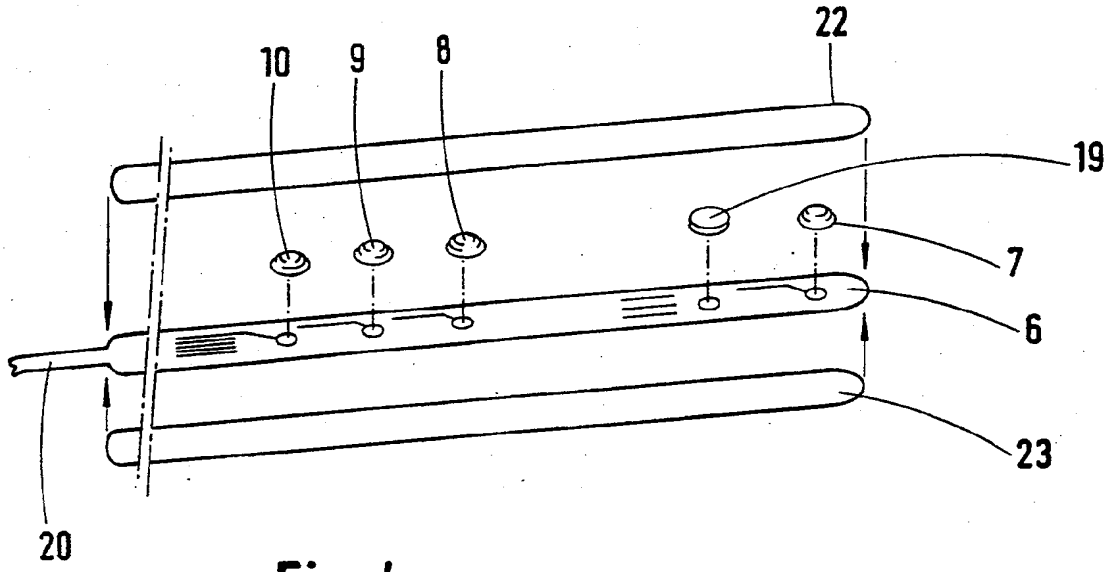


Fig.4

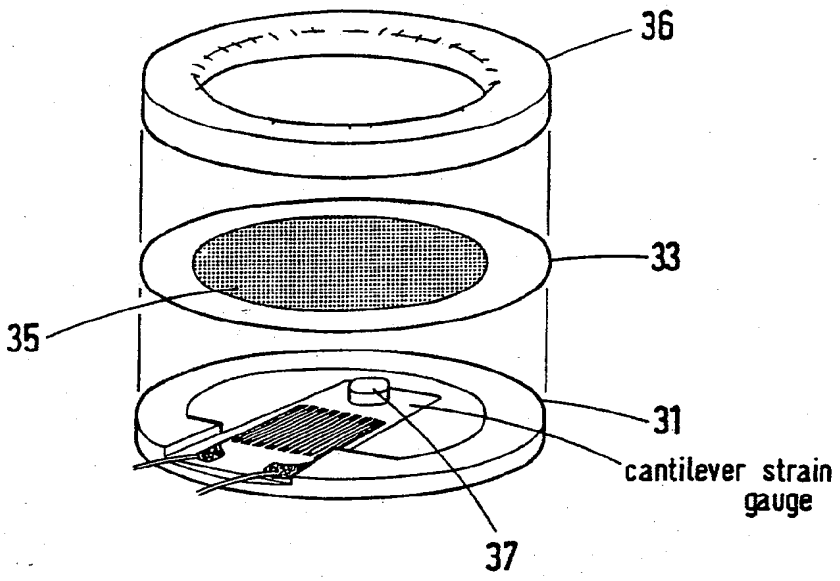

36
33
35
31
cantilever strain gauge
37

Fig.5

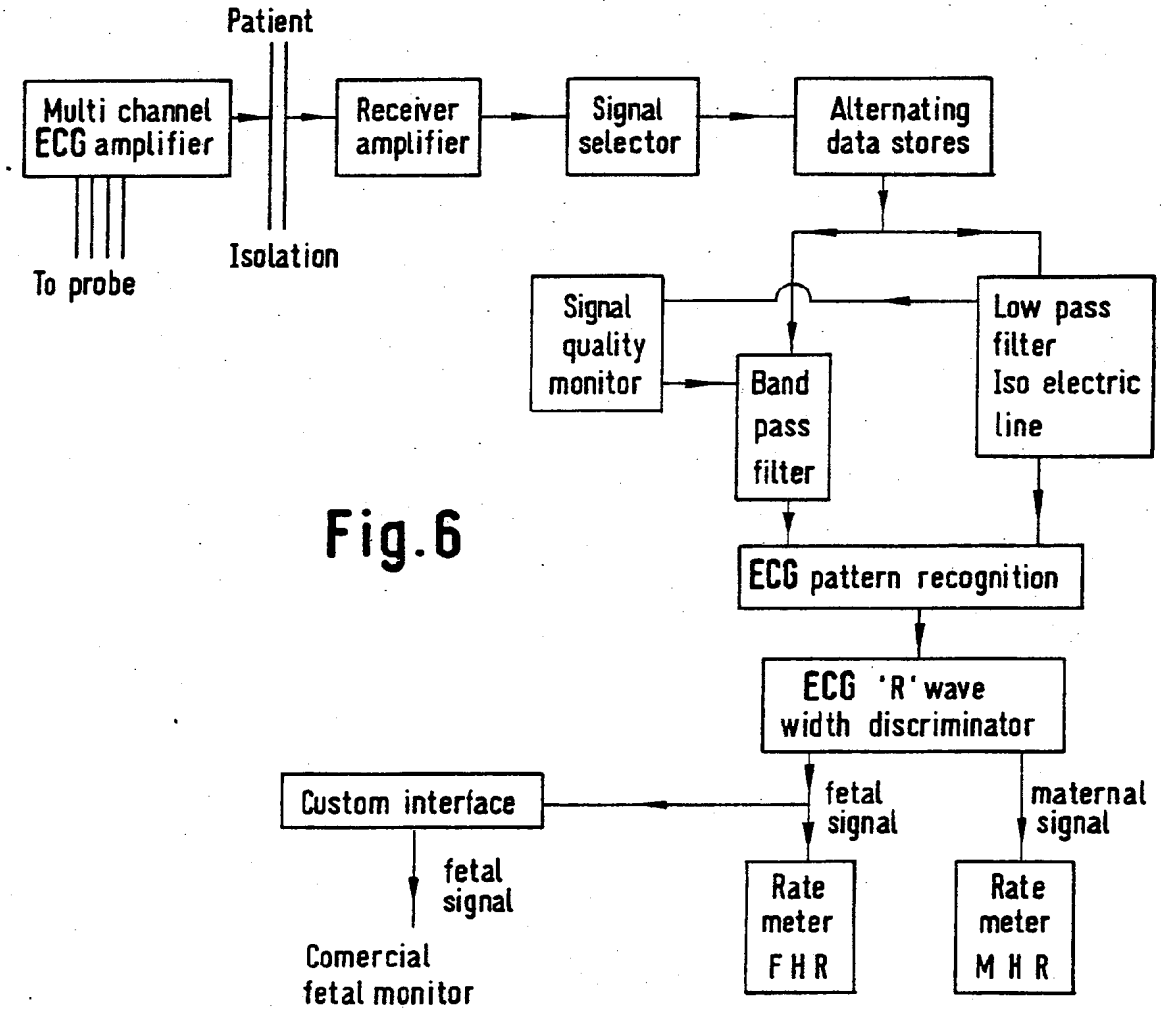

Patient
Multi channel ECG amplifier
Receiver amplifier
Signal selector
Alternating data stores
To probe
Isolation
Signal quality monitor
Band pass filter
Low pass filter Iso electric line
ECG pattern recognition
ECG 'R' wave width discriminator
Custom interface
fetal signal
maternal signal
fetal signal
Comercial fetal monitor
Rate meter FHR
Rate meter MHR

Fig.6

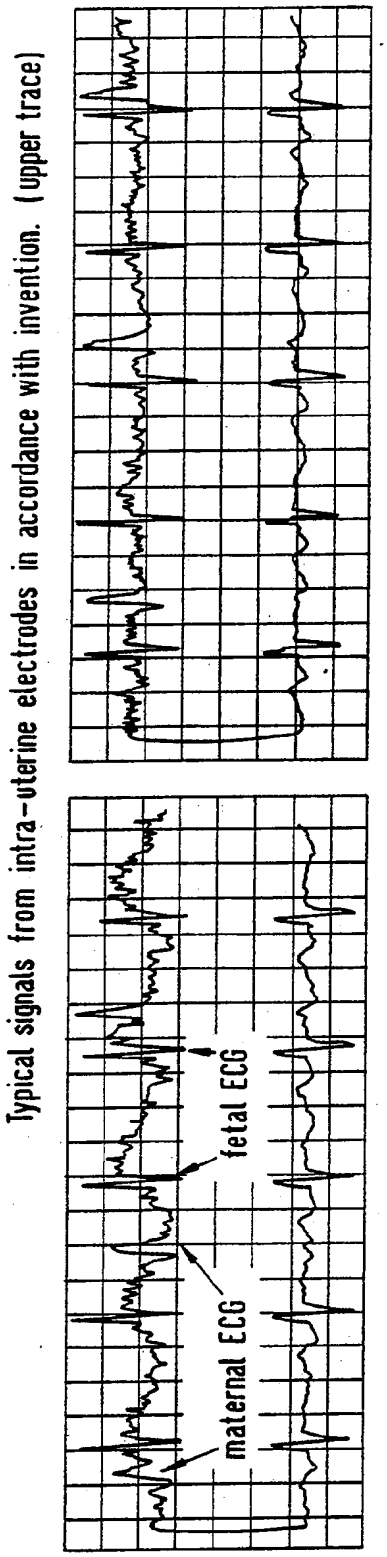

Typical signals from intra-uterine electrodes in accordance with invention. (upper trace)
fetal ECG
maternal ECG
Typical output from scalp-clip electrode. (lower trace)

Fig.7

INTERNATIONAL SEARCH REPORT

International Application No PCT/GB 87/00713

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [6]

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC[4]: A 61 B 5/04; A 61 B 5/03

II. FIELDS SEARCHED

Minimum Documentation Searched [7]

Classification System	Classification Symbols
IPC[4]	A 61 B

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [9]

Category *	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No. [13]
X	US, A, 3326207 (J.J. EGAN) 20 June 1967 see column 2, lines 15-58; column 3, lines 10-25, 54-60; column 4, line 66 - column 5, line 13; figures 1-6 --	1,4,5,8
A	GB, A, 2016706 (D.E. MAYNARD) 26 September 1979 see abstract; page 1, lines 69-79; page 1, line 119 - page 2, line 5; page 2, lines 45-55, 107-109; page 4, line 130 - page 5, line 24; page 6, lines 20-29; figures 1-3,8B --	1,4-8
A	EP, A, 0092982 (AMERICAN HOME PRODUCTS CORP.) 2 November 1983 see abstract; page 3, lines 5-15; page 4, lines 4-31; figures 1,2 --	1,4-8
A	FR, A, 2020437 (F. HOFFMANN-LA ROCHE ET CIE.) 10 July 1970 see page 2, lines 8-13; page 3, line 10 - page 4, line 33; page 5, lines	1,2,5,6 ./.

* Special categories of cited documents: [10]

"A" document defining the general state of the art which is not considered to be of particular relevance

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
12th January 1988	19 FEB 1988
International Searching Authority	**Signature of Authorized Officer**
EUROPEAN PATENT OFFICE	P.C.G. VAN DER PUTTEN

FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

A	US, A, 3545432 (R.M. BERMAN) 8 December 1970 see abstract; column 1, lines 47-56; column 2, lines 21-31; column 3, lines 16-52; figure 5 ------	2-4

V. [X] OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE [1]

This International search report has not been established in respect of certain claims under Article 17(2) (a) for the following reasons:

1. [X] Claim numbers 8, because they relate to subject matter not required to be searched by this Authority, namely:

See Rule 39.1(iv) PCT: Methods for treatment of the human or animal body by surgery or therapy, as well as diagnostic methods.

2. [ ] Claim numbers ....., because they relate to parts of the International application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claim numbers ....., because they are dependent claims and are not drafted in accordance with the second and third sentences of PCT Rule 6.4(a).

VI. [ ] OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING [2]

This International Searching Authority found multiple inventions in this international application as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims of the international application.

2. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the international application for which fees were paid, specifically claims:

3. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim numbers:

4. [ ] As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee.

Remark on Protest

[ ] The additional search fees were accompanied by applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO. GB 8700713 SA 18999

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on 01/02/88
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US-A- 3326207		None	
GB-A- 2016706	26-09-79	US-A- 4308873	05-01-82
EP-A- 0092982	02-11-83	JP-A- 58192532	10-11-83
FR-A- 2020437	10-07-70	NL-A- 6914767	14-04-70
		DE-A- 1950197	17-12-70
		US-A- 3572322	23-03-71
		CH-A- 512235	15-09-71
US-A- 3545432	08-12-70	None	